

REMARKS/ARGUMENTS

Claims 1-14, 31, 32, 54, 69, 71, 73 and 75 were pending. Claims 7, 13-30 and 33-83 are now canceled. Claims 1-6 and 31 have been amended. No new matter is added. Applicants respectfully request reconsideration of the rejections.

Claims 2-5 have been objected to as being of improper dependent form. The claims have been amended in accordance with the Examiner's suggestions.

Claims 1-14, 32 and 33 have been rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-21 and 24-31 of U.S. Patent no. 6,676,935; or claims 1-17 of U.S. Patent no. 6,432,700; or claims 1-8 and 11-15 of U.S. Patent no. 6,495,130.

Obviousness-type double patenting of an application claim is only applicable when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103, except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art.

Applicants respectfully submit that the presently claimed invention is not made obvious by the claims of the cited patents. Claims 1-13 are directed to polynucleotide sequences having enhancer activity. The claims of the cited patents are directed to adenoviral vectors comprising an adenoviral gene required for replication and operably linked to a TRE. The specific sequence set forth in the presently pending claims is not made obvious by the use of an hK2-TRE in an adenoviral construct.

Why not cite the prior art?

Claims 14, 31 and 32 have been rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-20 and 22-26 of U.S. Patent no. 6,436,394; or claims 1-26 and 28-54 of U.S. Patent no. 6,197,293.

Claim 31, which is presently pending, is directed to an adenoviral vector comprising nucleotides 8021 to 8371 of SEQ ID NO:1. Applicants respectfully submit that the construct comprising this specific sequence is not obvious in view of the claims of the '394 or '293 patent. *Why?*

Claim 14 has been canceled, rendering moot the rejection under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-11 of U.S. Patent no. 6,051,417. *Why?*

Claims 1-13 have been rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-22 of U.S. Patent no. 6,585,968, or claims 1-20 and 22-26 of U.S. Patent 6,436,394, or claims 1-26 and 28-54 of U.S. Patent no. 6,197,294.

Applicants respectfully submit that the presently claimed invention is not made obvious by the claims of the cited patents. Claims 1-13 are directed to polynucleotide sequences having enhancer activity. The claims of the cited patents are directed to adenoviral vectors comprising an adenoviral gene required for replication and operably linked to a TRE. The specific sequence set forth in the presently pending claims is not made obvious by the use of an hK2-TRE in an adenoviral construct. *Why?*

Claims 1-13 have been rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-11 of U.S. Patent no. 6,051,417.

Applicants respectfully submit that the presently claimed invention is not made obvious by the claims of the cited patents. Claims 1-14 are directed to polynucleotide sequences having enhancer activity. The claims of the cited patent is directed to screening methods to determine if a candidate compound alters prostate-specific expression. The specific sequence and specific adenoviral vector set forth in the presently pending claims is not made obvious by claimed methods, which do not recite the specific enhancer sequences or adenoviral vectors. *Revisions*

→ no adenoviral vector rejected

Applicants respectfully submit that the present claims are not obvious in view of the claims of the cited patents. However, in order to further prosecution, filing of a terminal disclaimer will be considered upon indication of otherwise allowable subject matter.

A provisional rejection has been made of claims 1-14, 31 and 32 over claims 1-28 of US Application 20030152553, or claims 1-9, 19, 22, 26-39, 41, 49-55, 59-63, 67 and 68 of US Application 20030118555, or claims 1-12, 14, 18-28, 41-43 and 47-58 of US Application 20030068307.

Applicants respectfully submit that in a provisional double patenting rejection it is proper to issue the present application, thereby converting the provisional rejection.

The rejections of Claim 7 and 14 under 35 U.S.C. 112, and 102, are made moot by the cancellation of the claim.

Claims 1-7, 31 and 32 have been rejected under 35 U.S.C. 112, first paragraph. Applicants have amended independent Claim 1 to recite that the claimed 150 contiguous nucleotides provide prostate-specific enhancer activity, in accordance with the Examiner's suggestions. In view of the above amendments, withdrawal of the rejection is requested.

Claims 1-6 have been rejected under 35 U.S.C. 112, first paragraph. The Office Action states that the claims are not adequately enabled, stating that only polynucleotides having enhancer activity and comprising nucleotides 8021-8371 of SEQ ID NO:1 are adequately enabled.

Applicants respectfully submit that the sequence set forth in SEQ ID NO:1 is enabled for an enhancer polynucleotide as set forth in the present claims. Applicants respectfully wish to draw the Examiner's attention to Figure 10, which illustrates enhancer activity in regions of SEQ ID NO:1.

It is further noted that Table 1 provides evidence for substantial enhancer activity in regions of SEQ ID NO:1, which includes the constructs as presently claimed.

Table 1

Enhancer activity	5' end	3' end	Construct	Induction	Promoter
none	-324 11290	+33 12047	CN325	<10-fold ↑	minimal <i>hKLK2</i>
none	-607 11407	+33 12047	CN299	<10-fold ↑	full <i>hKLK2</i>
enhancer activity (9.7 kb)	-12014 1	-2257 9765	CN322	30- to 90- fold ↑	full <i>hKLK2</i>
enhancer activity (3.7 kb)	-6038 5976	-2394 9620	CN355	35-fold ↑	minimal <i>hKLK2</i>
enhancer activity (1.8 kb)	-5155 6859	-3387 8627	CN379	81-fold ↑	minimal <i>hKLK2</i>
enhancer activity (1.17 kb)	-4814 7200	-3643 8371	CN390	90-fold ↑	minimal <i>hKLK2</i>
"core regulator" (350 bp)	-3993 8021	-3643 8371	CN396	37-fold ↑	minimal <i>hKLK2</i>
enhancer activity (1.8 kb)	-5155 6859	-338 8627	CN408	80-fold ↑	SV40

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One of skill in the art can readily utilize the specific polynucleotide sequence of SEQ ID NO:1, in combination with the assays and guidance for determination of activity provided by Applicants, (see in particular the methods of Example 7), to determine a polynucleotide of at least 150 nt in length having enhancer activity.

Applicants respectfully submit that the present claims meet the requirements of 35 U.S.C. 112. Withdrawal of the rejection is requested.

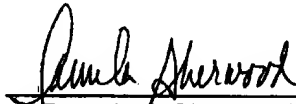
CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, she is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number CELL-011CON.

Respectfully submitted,

Date: June 1, 2004

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